510(k) Summary
Lotus®

510(k) Number K131427

OCT 24 2013

Manufacturer Identification

Submitted by:
Spinal Elements, Inc.
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Contact Information:
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Date Prepared: May 15, 2013

Proprietary Name	Lotus®
Common Name	Spinal Interlaminal Fixation and Spinal Intervetebral Fixation Orthosis and/or Pedicle Screw System
Device Classification	21 CFR 888.3050, and / or 21 CFR 888.3070
Proposed Regulatory Class	Class II
Device Product Code	KWP, MNI, MNH

Purpose of this Traditional 510(k)
This 510(k) seeks clearance for a line addition to the previously cleared (K120467) Lotus system and a minor modification to the indication for use by adding language relative to the device's ability to be used in conjunction with Spinal Elements' Mercury® system.

Device Description
The Spinal Elements Lotus Posterior Cervical/Thoracic System consists of a variety of fixation devices that are attached to the spine by means of screws and hooks placed in/or on the pedicles or posterior elements of the various vertebrae, rods that span the distance between the screws/hooks. Screws are intended for attachment to the thoracic (T1-T3) spine only. The system achieves fixation by the mechanical joining of the rods, screws, and hooks. A variety of constructs may be assembled to suit the individual pathology and anatomy of the patient.

Connectors
Connectors are offered in a variety of sizes and configurations and are manufactured from titanium alloy (Ti-6Al-4V) conforming to ASTM F 1472 and / or F 136. The following connectors are being added to the system:

- Offset connector
- Round offset connector
- Axial rod to rod connector
- Ø3.5mm Axial rod to rod connector
- Ø 5.5mm Axial rod to rod connector
- Parallel rod to rod connector
- Ø 3.5mm Parallel rod to rod connector
- Ø 5.5mm Parallel rod to rod connector
- Transition rods

Intended Use of the Device
The Spinal Elements Lotus Posterior Cervical/Thoracic Spinal System is intended for posterior fixation of the cervical and thoracic spine (C1-T3) for the following conditions: degenerative disc disease (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies); spondylolisthesis; spinal stenosis; trauma (fracture/dislocation); failed previous fusion; tumors. The Spinal Elements Lotus Posterior Cervical/Thoracic Spinal System may be used in conjunction with the Spinal Elements Mercury system for transition at T1 – T3.

The use of polyaxial pedicle screws is limited to placement in T1-T3 for treating thoracic conditions only. The screws are not intended to be placed in the cervical spine.

Performance Data
The following testing was performed:

- Static Compression Bending per ASTM F1717
- Dynamic Compression Bending per ASTM F1717
- Static Torsion testing per ASTM F1717
- Torsion testing per ASTM F1798
- Axial grip testing per ASTM F1798

Substantial Equivalence
Spinal Elements Posterior Cervical/Thoracic Spinal System is substantially equivalent to the previously cleared Spinal Elements Posterior Cervical/Thoracic Spinal System (Lotus) cleared in 510(k) K120467.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 24, 2013

Spinal Elements, Incorporated
Mr. Benjamin A. Kimball
Regulatory Affairs Manager
3115 Melrose Drive, Suite 200
Carlsbad, California 92010

Re: K131427
Trade/Device Name: Lotus® Posterior Cervical/Thoracic Spinal System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP, MNI, MNH
Dated: September 25, 2013
Received: September 26, 2013

Dear Mr. Kimball:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) K: K131427

Device Name: Spinal Elements Lotus® Posterior Cervical / Thoracic Spinal System

Indications for Use:
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Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K131427